



PATENT

## In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Qui, et al.

SERIAL NO.: 09/877,681

FILING DATE: June 8, 2001

TITLE: **CONTROLLED RELEASE  
FORMULATION OF DIVALPROEX  
SODIUM**

EXAMINER: not yet assigned

ART UNIT: 1615

DOCKET NO.: 6437.US.P4

I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner for Patents, Washington, D.C., 20231 on the date shown below.

*Sarah Mayhew*

Sarah Mayhew

Date

Assistant Commissioner for Patents  
Washington, D.C. 20231

*cf Prior art w/ att*  
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OCT 03 2001  
TECH CENTER 1600/2900

*Best*  
*11-11-01*

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

In accordance with their duty of disclosure under 37 C.F.R. §1.56, and as authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05(b), Applicants submit herewith certain patent documents, publications and/or other information ("references") which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The identification of any reference herein is not intended to be and should not be understood as being an admission that such reference necessarily constitutes "prior art" within the meaning of applicable law.

The cited references are listed on attached form PTO-1449.

- ☒ A copy of each cited reference is provided;
- ☐ Copies of cited references are not provided because each has previously been made of record in the parent application, or is otherwise known to be in the Examiner's possession.

The Examiner is requested to review and evaluate each cited reference to make an independent assessment of the materiality of each, if any, to the examination of the above-identified application. The Examiner is requested to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the present invention. The copies being submitted with this Statement are the best copies available at this time. Applicants respectfully request that (1) the references cited herein be made of record; (2) that the Examiner acknowledge his consideration of each reference by initialing and returning the enclosed copy of the PTO-1449 form; and (3) that such references appear on the printed patent as having been considered on the record.

With regard to payment of a fee:

- ☒ No fee is due because:
- ☒ This Statement is mailed within three months of the filing date of this application, or before the mailing date of a first office action on the merits (see 37 C.F.R. §1.97(b)).
- ☐ Applicants certify that each reference cited in this Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement. (see 37 C.F.R. §1.97(e)).
- ☐ This Statement is filed after the mailing date of a first Office Action on the merits but before the mailing date of either a final action or a Notice of Allowance (see 37 C.F.R. §1.97(c)) so a fee of **\$180.00** is specified by 37 C.F.R. §1.17(p).


If any fees are owed, or any credit is due pertaining to this case, please charge that fee or apply that credit to Deposit Account No. 01-0025. A duplicate sheet of this page is enclosed.

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Respectfully submitted,

  
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FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6437.US.P4	Serial No.: 09/877,681
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant Qui, et al.	Group: 1615
		Filing Date: 06/08/01	

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
	5,017,613	05/21/91	Aubert, et al.			
	6,077,542	06/20/00	Sherman			
	6,150,410	11/21/00	Engh, et al.			

## FOREIGN PATENT DOCUMENTS

Document Number	Date	Name	Class	Subclass	Translation (Yes No)
EP 0 430 287 B2	06/05/91				
EP 0 141 267 B1	08/05/87				
WO 00/45793 A1	08/10/00				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Abstract of Collins, et al., "Extended Release Formulations of Anticonvulsant Medications Clinical Pharmacokinetics and Therapeutic Advantages", CNS Drugs, New Zealand, 2000, 14/3 (203-212)
	Abstract of Bialer, et al., "Criteria to Assess in Vivo Performance and Bioequivalence of Generic Controlled-Release Formulations of Carbamazepine", Epilepsia, United States, 1998, 39/5 (513-519)
	Abstract of Chun, et al., "Multiple-dose Evaluation of the Absorption Characteristics of Divalproex Sodium Tablets, a Delayed-Release Preparation of Valproate, in Healthy Volunteers", Clinical Drug Investigation, New Zealand, 1995, 10/1 (40-47)
	Abstract of Bressolle, et al., "A Double Weibull Input Function Describes the Complex Absorption of Sustained-Release Oral Sodium Valproate", Journal of Pharmaceutical Sciences, United States, 1994, 83/10 (1461-1464)
	Abstract of Hussein, et al., "Pharmacokinetics of Valproate after Multiple-dose Oral and Intravenous Infusion Administration: Gastrointestinal-related Diurnal Variation", Journal of Clinical Pharmacology, United States, 1994, 34/7 (754-759)
	Abstract of Wilder, et al., "Gastrointestinal Tolerance of Divalproex Sodium", Neurology, United States, 1983, 33/6 (808-811)
	Abstract of Wilder, et al., "Twice-daily Dosing of Valproate with Divalproex", Clinical Pharmacology and Therapeutics, United States, 1983, 34/4 (501-504)
EXAMINER	DATE CONSIDERED:

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw Line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.